Title: Increasing HPV Vaccination Rates through Virtual Immersive Communication Training on Recommending Immunizations: An Efficacy Study of VICTORI

NCT: NCT04368455

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Title of research study: ***Increasing HPV Vaccination Rates through Virtual Immersive Communication Training on Recommending Immunizations: An Efficacy Study of VICTORI (AIM 2: PPCC Physician)***

Key Information:

The following is a short summary of this study to help you decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

Investigator:

F. Joseph Real, MD, MEd

Contact Info:

To contact the research coordinator working with this study (Andrea Meisman), call 513-803-3132

Protocol #:

2019-0829

If you are 18 years and older: This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study. If you sign this form, you will receive a signed copy of it for your records.

Reason for the study:

The main reason for this research study is to assess the impact of Virtual Immersive Communication Training on Recommending Immunizations (VICTORI) on adolescents' HPV vaccination rates as well as the impact of the curriculum on physicians' knowledge, attitudes, perceptions, confidence, and vaccine recommendation behaviors.

Procedures:

You will be asked to complete a pre-survey (estimated 15 minutes) to assess your HPV and HPV vaccine knowledge, attitudes, perceptions, confidence, and vaccine recommendation behaviors. Next, you will be asked to complete a self-directed review of an app-based curriculum focused on HPV vaccination. This will take about 30 minutes. After the completion of the app-based curriculum, you will be asked to schedule a time convenient for you to complete four virtual reality (VR) simulations related to recommending the HPV vaccine (estimated 20 minutes) in-person or through Zoom. Following the simulations, you will be asked to complete an immediate post-survey to assess the same components from the pre-survey. Three months later, you will be asked to complete the same post-survey. All of the surveys will be emailed to you through REDCap.

More detailed information about the study procedures can be found under ***"(Detailed Procedures)"***

Risks to Participate:

Although the researchers have tried to avoid risks, you may feel that some questions that are asked of you will be stressful or upsetting. You do not have to answer anything you do not want to.

Benefits to Participate:

You may learn about the HPV vaccine and increase your knowledge, attitudes, perceptions and confidence related to recommending the HPV vaccine.

Other Options:

Participation in research is completely voluntary. Your decision to participate or not to participate will not impact your evaluation. Your alternative to participating in this research study is to not participate.

Payment:

If you agree to take part in this research study, we will pay you $50 total for your time and effort. You will receive $40 after completing the pre-survey, app curriculum, VR simulation, and immediate post survey. You will receive an additional $10 after completing the three month follow up survey.

You will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you a handout that will explain how to use the card. Because you are being paid for your participation, Cincinnati Children's is required by the Internal Revenue Service (IRS) to collect and use your social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form will be given to the Cincinnati Children's business office. It will not be kept as part of your study chart. If you move, you will need to complete another W-9 with an updated address.

Additional Study Information:

The following is more detailed information about this study in addition to the Key Information.

If I have Questions or would like to know about:

Who to talk to…	**You can call …**	**At …**
• Emergencies • General study questions • Research-related injuries	**F. Joseph Real, MD, MEd**	Phone: 484-716-3867

Who to talk to…	You can call …	At …
• Any research concerns or complaints		
• Your rights as a research participant	**CCHMC Institutional Review Board (IRB)** This is a group of scientists and community members who make sure research meets legal and ethical standards.	Phone: (513) 636-8039

Detailed Procedures:

You will be asked to complete a pre-survey (estimated 15 minutes) to assess your HPV and HPV vaccine knowledge, attitudes, perceptions, confidence, and vaccine recommendation behaviors. Next, you will be asked to complete a self-directed review of an app-based curriculum focused on HPV vaccination. This should take about 30 minutes. After the completion of the app-based curriculum, you will be asked to schedule a time convenient for you to complete four virtual reality (VR) simulations related to recommending the HPV vaccine. After each scenario, the facilitator will provide you with feedback regarding your use of evidence-based communication skills. These four simulations will take approximately a total of 20 minutes (5 minutes for each simulation) and they will be audio and video recorded. Following the simulations, you will be asked to complete an immediate post-survey to assess the same components from the pre-survey. Three months later, you will be asked to complete the same post-survey. All of the surveys will be emailed to you through REDCap.

In addition, we will obtain data from the EPIC electronic medical record regarding your patients' HPV vaccination status on a monthly timeline 6 months prior to you completing the intervention, the months during intervention implementation, and 13 months after the intervention. However, this will not require you to complete any actions or tasks.

Change of Mind/Study Withdrawal:

You can leave the research at any time; it will not be held against you.

Privacy:

Information about you will be kept private by having research records stored securely and only allowing the research team to have access to the records. Your information will be kept in REDCap, which has security measures in place for confidential data storage. Audio

and video recordings will be stored on the secure CCHMC shared drive. After three years, raw data will be deleted and destroyed by Dr. Real. Only research team members will have access to the data. The data from this research study may be published; but you will not be identified by name. Agents of CCHMC may inspect study records for audit or quality assurance purposes.

Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

PARTICIPATION ACKNOWLEDGMENT

Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research, you will document your permission by indicating "Yes, I consent to participate in the study" below.

You will receive a copy of this document for your records.

Do you consent to the study?

____ Yes, I consent to participate in the study

____No, I DO NOT consent to participate in the study